

## **REMARKS**

### **I. Status of the Claims**

Claims 1 through 19 and 22 through 47 are pending.

Claims 20 and 21 have been canceled.

Claims 22 through 25 are amended in a manner that is believed to overcome rejections contained in the pending Office Action. The amendments to the claims have been made solely for reasons of clarity. Support for these amendments can be found throughout the drawings, specification and claims as originally filed. No new matter or issues are believed to be introduced by these amendments.

### **II. Amendments**

A. **Claim 22** -- Permission to amend claim 22 is requested. This amendment is to comply with the rejection for lack of antecedent basis. Claim 22 is amended to incorporate the limitations of canceled Claim 20 and to correct reference to "stabilization solution" by conforming it to the existing term "stabilization buffer." No new issues of patentability are raised.

B. **Claims 23-25** -- Permission to amend claims 23-25 is requested. This amendment is to comply with the rejection for lack of antecedent basis. Claim 23 is amended to incorporate the limitations of canceled Claim 20 and to correct reference to "formulation solution." No new issues of patentability are raised.

C. **The specification** -- The specification is amended to correct obvious typographical errors in numbering of the Examples. Through mis-numbering, Example numbers 7 and 16 are not found. There are 20 examples in total and not 22 examples. The specification has been amended to correctly number the examples as 1 through 20, and the intra-examples numbers advanced accordingly. No new matter has been added.

### **III. Claims 20-21 are rejected under 35 U.S.C. 102(b) as anticipated by Lee et al.**

The Examiner has rejected Claims 20 and 21. Claims 20 and 21 have been withdrawn. In an excess of caution and to be fully responsive, Applicant notes that the last sentence of the

paragraph presenting this rejection refers to "claims 17-19.". Applicant believes that reference to "claims 17-19" was a typographical error and claims 20 and 21 were the intended reference.

**IV. New Rejection -- Claim Rejections, 35 U.S.C. § 112, first paragraph**

Claims 1 through 47 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. This rejection is respectfully traversed.

**A. The Examiner's Rejection** – The Examiner stated that the claims are drawn to the isolation of a bioactive polypeptide.

"However, the applicant has not shown to a person of skill in the art that he/she had possession of the invention at the time of filing of the present application. In order to show to a person [of?] skill in the art that the polypeptide isolated using the method has bioactivity or is 'bioactive', the applicant would need to provide a biological assay that demonstrates the activity of said isolated polypeptide." Office Action of July 14, 2004, at 5.

**B. Applicant's disclosure** – As noted by the Examiner, Applicant states that bioactivity is determinable in vitro and in vitro by carrying out suitable known bioassays. The Examiner makes reference to one such bioassay (Orsini) as known. One example of a bioassay is referenced at page 6, lines 4-6 of the specification. Various protein specific bioassays are noted: fish somatotropin, at page 44, line 22 *et seq.* and 50, line 17, *et seq.*. Troponin subunit bioassays are presented at page 57 line 19 *et seq.*; with reference to US 5,837,680 at page 58, line 23; page 59, line 9 *et seq.* and page 59, line 25. Bioassays based on mammalian cell systems are cited at page 60, lines 6-13. Bioassays based on bacterial expression systems are cited at page 60, lines 14-16. Bioassays based on baculovirus and insect systems are cited at page 60, lines 16-24. Bioassays based on yeast protein expression technology are cited at page 60, line 25 continuing to page 61, line 1. Bioassays based on fungal expression systems are cited at page 61, lines 2-12.

**C. The Deficiency of the Rejection** -- The invention is a method of broad application directed toward isolation of proteins without inactivation. The number of proteins to which this applies is infinite. The requirement of 35 U.S.C. § 112, first paragraph does not require the specification to be a blueprint. Staehelin v. Secher, 24 USPQ2d 1513, 1516 (BPAI 1992). The

specification best omits what is well known in the art. *See, In re Buchner*, 929 F.2d 660, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991).

The facts here are similar to those of *Ajimoto Co. v. Archer-Daniels-Midland Co.*, 56 USPQ2d 1332 (CA FC 2000). The patent at issue describes and claims the modification of bacteria in order to block both the regulatory mechanism that limits amino acid production and the degradation pathway for the amino acid that is produced, leading to bacterial overproduction of the amino acid. A bacterium modified to be "feedback resistant" to the production of threonine and thus "overproduce" threonine. The patent was challenged as not enabled in failing to adequately teach (i) how to identify the specific amino acid genes in the donor bacterium, (ii) how to obtain a chromosome DNA fragment, (iii) how to obtain suitable plasmids, (iv) how to isolate recipient bacterial strains, and (v) how to perform a transformation step. *Id.*, at 1337. The Federal Circuit found enablement citing with approval the holding of the district court that "all of the methods needed to practice the invention were well known to those skilled in the art." *Id.*

In fact the court advised against including known information.

"Requiring inclusion in the patent of known scientific/technological information would add an imprecise and open-ended criterion to the content of patent specifications, could greatly enlarge the content of patent specifications and unnecessarily increase the cost of preparing and prosecuting patent applications, and could tend to obfuscate rather than highlight the contribution to which the patent is directed. A patent is not a scientific treatise, but a document that presumes a readership skilled in the field of the invention. *Id.*, (citation omitted).

Applicant particularly responds to the aspect of the rejection stated as "the applicant has not shown to a person of skill in the art that he/she had possession of the invention at the time of filing of the present application." Office Action of July 14, 2004, at 5. It is respectfully noted that Applicants are not required to convince. Certainly, in the absence of evidence or apparent reason why the invention does not perform as claimed, the allegation of utility in the Specification must be accepted as correct. *In re Bundy*, 209 USPQ 48 (CCPA 1981). The presumption is, thus, in favor of utility, in the absence of contrary data.

Applicant respectfully requests that the instant rejection be withdrawn.

**D. Rejections based on missing Example 7**

Claims 1 through 47 stand rejected based on the absence of Example 7. This rejection is respectfully traversed.

As noted above, through mis-numbering, Example numbers 7 and 16 are not found. There are 20 examples in total and not 22 examples. By substitute specification, the specification is amended to correct obvious typographical errors in numbering of the examples. The specification has been amended to correctly number the examples as 1 through 20, and the intra-example reference numbers advanced accordingly. A red lined version and a clean version of the substitute specification is enclosed herewith.

**V. Claim Rejections, 35 U.S.C. § 112, second paragraph**

Claims 21-25 are rejected under 35 U.S.C. § 112, second paragraph, as indefinite. Claim 21 has been cancelled. As to claims 22 through 25, this rejection is respectfully traversed.

A. **Claim 22** – Claim 22 is held indefinite in lacking antecedent basis for the term “stabilizing solution”

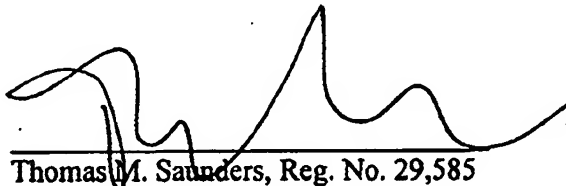
**VI. Extra Claims**

Two claims have been canceled: one independent and one dependent. Two dependent claims have been amended into independent form. Authorization is hereby given to charge Deposit Account No. 50-0369 in connection with any fees necessary.

**CONCLUSION**

The claims remaining within the application are believed to patentably distinguish over the prior art and to be in condition for allowance. Early and favorable consideration of this application is respectfully requested.

Respectfully submitted,



Thomas M. Saunders, Reg. No. 29,585  
Attorney for Applicants  
Customer No. 21710  
Brown Rudnick Berlack Israels LLP  
One Financial Center, Box IP  
Boston, MA 02111  
Tel: (617) 856-8284  
Fax: 617-856-8201  
Email: ip@brbilaw.com

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